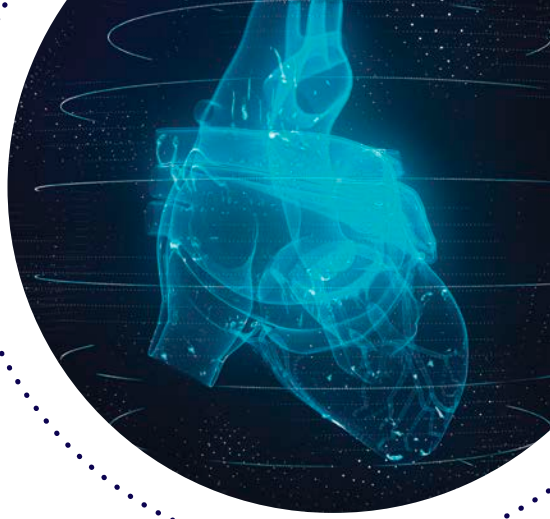
Medtronic

# LINQ family of ICMs




| Parameter | Reveal LINQ™ ICM[1] + TruRhythm™ detection | LINQ II™ ICM + AccuRhythm™ AI algorithms[2] |
|---|---|---|
| **Longevity** | 3 years | 4.5 years† |
| **Electrode spacing** | 38 mm | 40 mm |
| **Volume** | 1.2 cc | 1.4 cc |
| **Mass** | 2.5 g | 3.4 g |
| **Episode storage** | 59 min | 61 min |
| **Monitoring option** | Home monitor | Home monitor and mobile app |
| **Patient symptom mark** | Patient assistant | Mobile app or patient assistant |
| **Cardiac Compass™** | Yes | Yes |
| **MRI compatibility** | 1.5 and 3T | 1.5 and 3T |
| **Clinician notification** | Nightly transmission/CareAlert™ notifications | Between 5–6 a.m. clinic time daily transmission/ CareAlert notifications |
| **Telemetry** | Inductive (Tel B)<br>One-directional RF (MEDS) | Bluetooth® Low Energy<br>Two-way communication |
| **Algorithms** | **Detection algorithms**<br>P-SENSE detection<br>TruRhythm detection<br>• Pause<br>• Brady<br>• AF | **Detection algorithms**<br>Enhanced TruRhythm<br>• Pause enhancement<br>• Tachy: require rapid onset<br>• Brady: nighttime storage<br>• PVC burden<br>**Cloud-based AccuRhythm AI**<br>• AF algorithm<br>• Pause algorithm |
| **Remote programming** | No | Yes |
| **CareLink™ network** | Yes | Yes |

† Nominal settings.
[1] Reveal LINQ LNQ11 ICM Clinician Manual. M958488A001, Rev D.
[2] LINQ II LNQ22 ICM Clinician Manual. M974764A001D.

**Brief Statements**
**Medtronic LINQ Family Insertable Cardiac Monitor System (ICM) and Remote Monitoring**

**Indications**
The LINQ Family of Insertable Cardiac Monitors (ICMs) which includes Reveal LINQ ICM and LINQ II ICM are insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.

**Contraindications**
There are no known contraindications for the insertion of the LINQ Family ICM's or their accessories. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

**Warnings and precautions**
Patients with a LINQ Family ICM should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI Warnings, Precautions and Guidance Manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the LINQ II or Reveal LINQ ICM MRI Technical Manual.

Wireless accessories available for use with a LINQ Family ICM may experience connectivity or performance issues. See product manuals for details and troubleshooting instructions.

**Potential adverse events**
Potential adverse events from the LINQ Family ICM include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

There are no known adverse events associated with the use of any LINQ Family ICM wireless accessories.

*See the device manuals for detailed information regarding the implant procedure, indications/intended use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at (800) 328-2518 (Technical Services), (800) 551-5544 (Patient Services), and/or consult Medtronic's website at* www.medtronic.com.

**Caution:** Federal law (USA) restricts prescription devices to sale by or on the order of a physician.

**AccuRhythm AI ECG Classification System**

**Intended Use:** The intended use of the system is to reduce false positive cardiac arrhythmia episodes.

**Contraindications:** There are no known contraindications for AccuRhythm AI Models ZA400, ZA410, or ZA420.

**Precaution:** The AccuRhythm AI ECG classification system may incorrectly adjudicate a true positive episode as an AI false episode, causing that episode to be suppressed in the remote monitoring system.

*See the device manual for detailed information regarding the intended use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Medtronic Technical Services at 1-800-328-2518 and/or consult Medtronic's website at* medtronic.com.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.



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